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10-10-2003

Date

Terrie Lindquist

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: §

Jingwu Z. Zhang et al.

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Docket No.: 057186.000003

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Art Unit:

Unknown

Serial No.: 10/612,468

Examiner:

Unknown

Filed:

07/02/2003

§

For:

T CELL RECEPTOR CDR3 SEQUENCE AND METHODS FOR DETECTING AND

TREATING RHEUMATOID ARTHRITIS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing are the following documents:

- 1. Information Disclosure Statement;
- 2. Our return postcard, which we would appreciate your date stamping and returning to us upon receipt.

I hereby authorize the Commissioner for Patents to charge any additional fees that may be required or credit any overpayment to Bracewell & Patterson Deposit Account No. 50-0259 (Order No. 57186.3).

Date: Out. 10, 2003

Respectfully submitted,

J. Wendy Davis, Registration No. 46,393 BRACEWELL & PATTERSON, L.L.P.

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In compliance with Applicant's duty of candor and good faith in accordance with the provisions of 37 C.F.R. § 1.56, § 1.97, and § 1.98, Applicant files this Information Disclosure Statement and attached Form PTO-1449 listing references of which Applicant is aware.

INFORMATION DISCLOSURE STATEMENT

This Information Disclosure Statement is being filed before issuance of the first Office Action and no fee is required. In the event any fee is required, the Commissioner is hereby authorized to charge Bracewell & Patterson Deposit Account No. 50-0259 (57186.3).

Respectfully submitted,

Date: Out. 10, 2003

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Houston, Texas 77208-1389 Direct Phone: (713) 221-3301 Direct Fax: (713) 222-3287 ATTORNEY FOR APPLICANT Substitute of FORM A GA/PTO PRO MOBA (10-01) U.S. DEPARTMENT OF COMMERCE Patent and Trademark Office Complete if Known **Application Number** 10/612,468 Filing Date 07/02/2003 INFORMATION DISCLOSURE **First Named Inventor** Jingwu Z. Zhang et al. STATEMENT BY APPLICANT **Group Art Unit** Unknown **Examiner Name** Unknown (use as many sheets as necessary) **Attorney Docket Number** 057186.000003 Sheet of **U.S. PATENT DOCUMENTS** Name of Patentee or Applicant of Cited Document Publication Date MM-YYYY Pages, Columns, Lines, where Relevant Passages or Relevant Figures Appear Cite No. U.S. Patent Document Examiner Initials Kind Code (if

Cite	Foreign Patent Document			Publication Date MM-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevan Passages or Relevant Figures Appear
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		OTHER PRIOR ART
Examiner Initials	Cite No.	Include Name of Author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or county where published.
		Lee DM, Weinblatt ME. Rheumatoid arthritis. Lancet 2001;15:903-911.
		Firestein GS. Evolving concepts of rheumatoid arthritis. Nature 2003;423:356-361.
		Kerian-Candon S, Combe B, Vincent R, Clot J, Pinet V. Eliaou JF. HLA-DRB1 gene transcripts in rheumatoid arthritis. Clin Exp Immunol 2001;124:142-149.
		MacGregor A, Oilier W, Thomson W, Jawaheer D, Silman A. HLA~DRBI*0401/0404 genotype
		and rheumatoid arthritis: increased association in men, young age at onset, and disease severity. J Rheumatol 1995;22:1032-1036.
		Fries JF, Wolfe F, Apple R, Erlich H, Bugawan T, Holmes T, Bruce B. HLA-DRB1 genotype associations in 793 white patients from a rheumatoid arthritis inception cohort: frequency, severity, and treatment bias. Arthritis Rheum 2002;46:2320-2329.
		Dolhain RJEM, van der Heiden AN, Ter haar NT, Breedveld FC, Miltenburg AM. Shift towards T lymphocytes with a T helper 1 cytokine profile in the joints of patients with rheumatoid arthritis. Arthritis Rheum 1996; 12:1961-1969.
		Bemer B, Akca D, Jung T, Muller GA, Reuss-Borst MA. Analysis of Thi and Th2 cytokines expressing CD4+ and CD8+ T cells in rheumatoid arthritis by flow cytometry J Rheumatol 2000;27:1 128-1135.
		Davis LS, Cush JJ, Schultz-Koops H, Lipsky PE. Rheumatoid synovial CD4+ T cells exhibit a reduced capacity to differentiate into IL-4 poducing T helper-2 effector cells. Arthritis Res 2001;3:54-64.
		Goronzy JJ, Bartz-Bazzanella P, Hu W, Jendro MC, Walser-Kuntz DR, Weyand CM. Dominant clonotypes in the repertoire of peripheral CD4+ T cells in rheumatoid arthritis, J Clin Invest 1994;94:2068-2076.

.9	Goronzy JJ, Bartz-Bazzanella P, Hu W, Jendro MC, Walser-Kuntz DR, Weyand CM. Dominant
ADEMIE	clonotypes in the repertoire of peripheral CD4+ T cells in rheumatoid arthritis. J Clin Invest 1994;94:2068-2076.
	Gonzalez-Quintial R, Baccala R, Pope RM, Theofilopoulos AN. Identification of clonally expanded T cells in rheumatoid arthritis using a sequence enrichment nuclease assay. J Clin Invest 1996;97:1335-1343.
	Alam A, Lambert N, Lule H, Coppin H, Mazieres B, de Preval C, et al. Persistence of dominant T cell clones in synovial tissues during rheumatoid arthritis. J Immunol 1996; 156:3480-3485.
	Londei M, Savill CM, Verhoef A, Brennan F, Leech ZA, Duance V, et al. Persistence of collagen type IT-specific T-cell clones in the synovial membrane of a patient with rheumatoid arthritis. Proc Nati Acad Sci USA 1989;86:636-640.
	Pope RM, Pahiavani MA, LaCour E, Sambol S, Desai BY. Antigen specificity of rheumatoid synovial fluid lymphocytes. Arthritis Rheum 1 989;32:1371-1380.
	Devereux D, O'Hehir RE, McGuire J, van Schooten WC, Lamb JR. HLA-DR4Dw4-restricted T ce recognition of self antigen(s) in the rheumatoid synovial compartment. Int Immunol 1991;3:635-640.
	Res PC, Struijk L, Leow A, Daha MR, van den Elsen PC, Breedveld FC. Inflamed joints of patients with rheumatoid arthritis contain T cells that display in vitro proliferation to antigens present in autologous synovial fluid. Functional analysis on the basis of synovial-fluid-reactive T cell clones and lines. Hum Immunol 1994;40:291-298.
	Paliard X, West SF, Lafferty JA, Clements IR, Kappler JW, Marrack P, et al. Evidence for the effects of a superantigen in rheumatoid arthritis. Science 1991;253:325-329.
	Holoshitz J, Klajman A, Drucker I, Lapidot Z, Yaretzky A, Frenkel A, et al. T lymphocytes of rheumatoid arthritis patients show augmented reactivity to a fraction of mycobacteria cross-reactive with cartilage. Lancet 1986;2:305-309.
	Zagon G, Tumang JR, Li Y, Friedman SM, Crow MK. Increased frequency of V beta 17-positive I cells in patients with rheumatoid arthritis. Arthritis Rheum 1994;37:1431-1440.
	Alam A, Lule J, Coppin H, Lambert N, Mazieres B, De Preval C, et a!. T -cell receptor variable region of the beta-chain gene use in peripheral blood and multiple synovial membranes during rheumatoid arthritis. Hum Immunol 1995;42:331-339.
	VanderBorght A, Geusens P, Vandevyver C, Raus J, Stinissen P. Skewed T-cell receptor variable gene usage in the synovium of early and chronic rheumatoid arthritis patients and persistence of clonally expanded T cells in a chronic patient. Rheumatology 2000;39:1189-1201.
	Jenkins RN, Nikaein A, Zimmermann A, Meek K, Lipsky PE. T cell receptor V beta gene bias in rheumatoid arthritis. J Clin Invest 1993;92:2688-2701.
	Williams WV, Fang Q, Demarco D, VonFeldt J, Zurier RB, Weiner DB. Restricted heterogeneity of T cell receptor transcripts in rheumatoid synovium. J Clin Invest 1992;90:326-333.
	Li Y, Sun GR, Tumang JR, Crow MK, Friedman SM. CDR3 sequence motifs shared by oligoclona rheumatoid arthritis synovial T cells. Evidence for an antigen-driven response. J lin Invest 1994;94:2525-2531.
	Mima T, Ohshima 5, Sasi M, Nishioka K, Shimizu M, Murata N, et a!. Dominant & shared T cell receptor beta chain variable regions of I cells inducing synovial hyperplasia in rheumatoid arthritis. Biochem Biophys Res Commun 1999;263:172-180.
	Davey MP, Burgoine GA, Woody CN. TCRB clonotypes are present in CD4+ T cell populations prepared directly from rheumatoid arthritis. Hum Immunol 1 997;55: 11-21.
	Even J, Lim A, Puisieux I, Ferradini L, Dietrich PY, Toubert A, et al. T-cell repertoires in healthy and diseased human tissues analysed by T-ce!! receptor beta-chain CDR3 size determination: evidence for oligoclonal expansions in tumors and inflammatory diseases. Res Immunol 1995;
	Tang J, Myracle AD, Allen S, Karita E, Musonda R, Fultz PN, et al. Novel alleles at the lymphotoxin alpha (LTalpha) locus mark extended HLA haplotypes in native Africans. Hum Immunol 2001;62:269-278.
	Nakao M, Janssen JW, Flohr T, Bartram CR. Rapid and reliable quantification of minima! residual disease in acute lymphoblastic leukemia using rearranged immunoglobulin and I-cell receptor loci by LightCyc!er technology. Cancer Res. 2000;60:3281-289.

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RADEMARKO	Hong J, Zang YC, Tejada-Simon MV, Kozovska M, Li S, Singh RA, et al. A common TCR V-I sequence in V beta 13.1 T cells recognizing an immunodominant peptide of myelin basic protein multiple sclerosis. J Immunol 1999;163:3530-3538.
	Moreland LW, Morgan EE, Adamson TC 3rd, Fronek Z, Calabrese LH, Cash JM, et al. T cell receptor peptide vaccination in rheumatoid arthritis: a placebo-controlled trial using a combination of Vbeta3, Vbeta14, and Vbeta17 peptides. Arthritis Rheum 1998;41:1919-1929.
	Moreland LW, Heck LW Jr, Koopman WJ, Saway PA, Adamson IC, Fronek Z, et al. V beta 17 T cell receptor peptide vaccination in rheumatoid arthritis: results of phase I dose escalation study. J Rheumatol 1996;23:1353-1362.

Examiner Signature	Date considered		
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